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Date: March 14, 2011

Signature: .....Quyen Nguyen/..... (Quyen Nguyen)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/824,936

Confirmation No.: 7289

Filing Date: April 14, 2004

Inventor(s): Vahid SAADAT et al.

Title: METHOD AND APPARATUS FOR OBTAINING  
ENDOLUMINAL ACCESS

Examiner: M. Kasztejna

Group Art Unit: 3779

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**APPELLANTS' REPLY BRIEF**

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Sir:

This is a Reply Brief filed in accordance with the provisions of 37 C.F.R. § 41.41  
in response to the Examiner's Answer mailed January 13, 2011.

## **RESPONSES TO ARGUMENTS RAISED IN EXAMINER'S ANSWER**

The Examiner's Answer includes several contentions that require a response. In particular, the "Response to Argument" section spanning pages 11-14 of the Examiner's Answer makes several points that are demonstrably incorrect, as shown below.

### **A. Khalili's "Fixed Camera" Cannot Constitute a "Working Lumen"**

In response to Appellants' argument that the Khalili camera 330 does not correspond with a "working lumen" recited in claims 31 and 65, the Examiner repeats the argument that the fixed camera is a "working" element that is provided within a "lumen." (Examiner's Answer pg. 11, referring to the camera 330 or the optical fiber discussed at Khalili ¶ 0049). In doing so, the Examiner relies upon an incorrect and unreasonable interpretation of the term "working lumen." Appellants submit that the construction of the term "working lumen" recited in the claims must be consistent with the specification and must be read "in light of the specification as it would be interpreted by one of ordinary skill in the art." In re Suitco Surface, Inc., No. 09-1418 (Fed. Cir. April 14, 2010) (citations omitted).

A recent Federal Circuit case is directly on point. In ERBE Elektromedizin GmbH v. Int'l Trade Comm'n, No. 08-1358 (Fed. Cir. May 19, 2009), the Federal Circuit court answered the question of whether a claim reciting an endoscope having a "working channel" would read on an endoscope having fixed optics installed in its distal end, holding that: "fixed optics do not involve a 'working channel.'" Id. In doing so, the court first noted that the specification labeled and described a fixed optics installation differently from a "working channel," and that "[n]owhere does the specification indicate that a 'working channel' can be a fixed optics installation." Id. Second, the court considered a dictionary definition of "working" to conclude that "a 'working channel' is not stationary (as with a fixed optics installation) but is a channel thorough which work or activity may be done during the procedure." Id. Finally, the court also noted that the claim language requiring each working channel to have "an opening at each end" suggested that the claim did not read on a fixed optics installation. Id.

The Federal Circuit court's analysis and interpretation of the term "working channel" in the ERBE Elektromedizin case is directly applicable to the interpretation of the term "working lumen" in the present case. As noted in Appellants' Appeal Brief:

The recitation in each of the claims of "a working lumen" or "at least two working lumens" refers to an open space(s), channel(s), or conduit(s) to be used for passage of diagnostic or therapeutic tools therethrough. This interpretation is supported by Appellants' specification, which consistently uses the terms to refer to such a structure. (See, e.g., ¶ 0002: "The elongate body may also include *a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough*, or for injection of fluids or to draw suction." See also ¶ 0048: "In FIG. 7, first steerable shaft 82a illustratively is shown with working lumen 86 that extends through the shaft, as well as through cable 84a and elongate body 72'. Exemplary grasper tool 90 *is shown advanced through lumen 86.*")

(Appeal Brief, pp. 13-14). In addition, as in the ERBE Elektromedizin case, Appellants' specification makes a clear distinction between a fixed optics installation (such as an optical fiber or video chip) and a "working lumen." For example, paragraph 0002 states:

Medical endoscopy entails the insertion of an elongate body into a body lumen, conduit, organ, orifice, passageway, etc. The elongate body typically has a longitudinal or working axis and a distal region, and a visualization element disposed near the distal region in-line with the working axis. The visualization element may comprise an optical fiber that extends through the elongate body, or a video chip having an imaging sensor, the video chip coupled to or including a signal-processing unit that converts signals obtained by the imaging sensor into an image. The elongate body **may also include** a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough, or for injection of fluids or to draw suction.

(Emphasis added). There is a distinction made in the foregoing description between a visualization element (*i.e.*, a fixed optics installation) on the one hand, and a "working lumen" on the other. The term "working lumen" is clearly not being used in a manner that would suggest that it encompasses a fixed camera.

Second, the ERBE Elektromedizin court's reference to the dictionary definition of "working" and its analysis based upon that definition is equally applicable to the claims at issue here. Appellants' specification is completely consistent with the referenced dictionary definition and supports the interpretation that a "working lumen" is a lumen through which work or activity may be done during a procedure. This proper interpretation would exclude a fixed camera.

Third, and finally, the claim language at issue in the present case is remarkably similar to that analyzed by the ERBE Elektromedizin court in that Appellants' claims each require the recited working lumen to have a "distal opening" that is alternately covered and uncovered (or exposed) by articulation of the articulating element. This is consistent with the interpretation of the term "working lumen" proposed by Appellants above, but would not be consistent with an interpretation that covers a fixed optics installation.

For all of these reasons, the Board should reject the Examiner's argument that the term "working lumen" may be interpreted to read on a fixed camera.

**B. Khalili's "Robotic Arm Image Detector" Embodiments Do Not Teach or Suggest All of the Elements Recited in the Claims**

As an additional argument, the Examiner relies upon an embodiment described by Khalili that includes an image detector carried on a separate robotic arm. (Examiner's Answer pp. 11-12, referring to Khalili ¶ 0066 and Fig. 7a). However, this "robotic arm image detector" embodiment does not teach or suggest several other limitations recited in the claims, including (at least) the following:

- the "at least one articulating element ... connected to the elongate body near or at its distal region by a linkage member ..." (claims 1 and 65); and
- the steps of "moving the articulatable element ... thereby at least substantially exposing a distal opening of a working lumen" and "passing a diagnostic or therapeutic tool through the working lumen ..." (claim 31).

The Examiner incorrectly conflates features of the Khalili "robotic arm image detector" embodiment described in reference to Fig. 7a with features of embodiments described by Khalili in reference to Figs. 13-16 that include robotic arms 312, 314, 316 attached to the distal ends of leaflets 302, 304, 306 formed on the distal end of the device. Khalili specifically described the "robotic arm image detector" feature in relation to the embodiments described in relation to Figs. 1-6. (See ¶ 0066 – "the above examples"). Nowhere does Khalili describe or suggest a device in which the "robotic arm image detector" feature is combined with the robotic arms 312, 314, 316 and leaflets 302, 304, 306 shown in Figs. 13-16.

**C. Khalili's Figure 15 Embodiment Does Not Disclose All Elements of Claims 31 or 65**

As an alternative argument relating to claims 31 and 65, the Examiner relies upon an embodiment described in reference to Figure 15 of the Khalili publication. (Examiner's Answer pp. 12-13). There are several errors in this analysis.

First, for the same reasons discussed above in Section A, the Examiner's proposed interpretation of the term "working lumen" to read on the robotic arm 360 and/or the rear arm section 364 is unreasonably broad. Moreover, Khalili does not describe a lumen of any kind extending through the portion of the Figure 15 drawing labeled "Elongate Body" at the top of page 13 of the Examiner's Answer. The Examiner's reference to that portion of the drawing as including a "working lumen" is therefore without support.

Second, in relation to claim 31, that claim recites:

moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body.

The Examiner identifies the Khalili leaflet 362 as the "articulatable element" and the robotic arm 360 as the "working lumen provided in the elongate body." In Khalili's Figure 15 embodiment, however, the robotic arm 360 moves *in concert with* the leaflet 362. The leaflet 362 therefore cannot be said to move "to a position out-of-line with the working axis" of the elongate body.

Finally, in relation to claim 65, that claim recites "at least two working lumens extending through the elongate body." The Examiner's Answer identifies the rear arm section 364 of the robotic arm 360 as one of the "working lumens," and identifies the shaft of the Khalili device as another "working lumen." As discussed above, the term "working lumen" does not reasonably cover an arm section of a robotic arm. Nor does the Khalili publication identify any structure contained in the shaft portion that would constitute a "working lumen."

**D. Khalili's Figure 13A-C Embodiment Does Not Disclose All Elements of Claims 1 or 65**

Regarding claims 1 and 65, the Examiner relies upon an embodiment described in reference to Figure 13A-C of the Khalili publication. (Examiner's Answer pg. 13). The Examiner states that "Khalili clearly discloses at least two working lumens 330, 332, 334 extending through the elongate body." Section A above discusses why it is improper to characterize the Khalili camera 330 as a "working lumen." As for the ports 332 and 334, even if it was correct for the Examiner to identify these ports 332, 334 as the "working lumens" recited in either of claims 1 or 65, there could be no anticipation of either claim because there would be no "articulating element" that alternately covers and uncovers these ports.

### CONCLUSION

For at least the reasons set forth above and the reasons set forth in Appellant's Appeal Brief, the claims currently pending in the application are patentable over the prior art of record, and the rejections of those claims under 35 U.S.C. §§ 102(e) and 103(a) are improper and should be withdrawn. Appellants respectfully request the Board to overturn the Examiner's rejections with instructions to allow the claims.

Respectfully submitted,

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